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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,935	03/06/2002	Adi Shefer	4686-110 US	7056

7590 06/16/2009

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,935	SHEFER ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2009* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,24,30,31,33,35,41,42,48 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,24,30,31,33,35,41,42,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12/12/08* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 03/30/2009; and IDS filed 12/12/2008.

Claims 1-8, 10-23, 25-29, 32, 34, 36-40, 43-47 have been canceled.

Claims 9, 24, 30, 31, 33, 35, 41, 42, 48 and 49 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/30/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9, 24, 30, 31, 33, 35, 41, 42, 48 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing as claims 30 and 33 recite: “said nanospheres or microspheres are formed of a hydrophobic material and a detachable protective layer attached to said single polymeric matrix layer”. Is the protective layer part of the microspheres? Claim 48 recite: “delivering said dermatological active agent said skin from said patch a detachable protective layer attached to said single polymeric”.

Claims 30, 33, 35 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: application of the patch to the skin for specific period of time. The claims recite applying or affixing the patch to the skin, and removing the patch by rinsing, however, the claims do not recite that the patch was left on the skin for certain time to provide the desired effect.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the layers of the patch other than the invisible layer. The claim recites "patch consisting of invisible polymeric water soluble material" The polymeric water soluble layer cannot stand by itself as a patch especially during handling and storage because the water soluble layer will be affected by environmental conditions such as moisture that might have deleterious effect on the water soluble polymers.

Claims that depend from claims 30, 33 and 48 are also rejected.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 30, 31, 33, 35, 41, 42, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,108,837 ('837) in view of US 5,780,047 ('047), US 5,667,798 ('798) and US 5,695,779 ('779).

Applicant's claims

Claim 30, 33, 35, and 48 as currently amended are directed to methods of using patch comprising a single invisible or translucent water soluble polymeric matrix layer wherein the water soluble polymeric matrix layer consisting of one or more materials selected from the group consisting of polyvinyl alcohol, polyvinyl pyrrolidone, and hydroxpropyl cellulose, or a combination thereof, and dermatological active ingredient that is encapsulated in spray dried nanospheres or microspheres dispersed in said polymeric matrix layer, said nanospheres or microspheres are formed of a hydrophobic material, and said single polymeric matrix layer is attached to detachable protective layer which is removed before use. The methods of using the patch include the steps of affixing the patch to the skin by moistening said skin, and said patch removed by rinsing said patch with water.

Claim 42 is directed to the set forth patch.

Determining the scope and contents of the prior art (MPEP*§ 2141.01)*

GB '837 teaches water soluble film made of film forming compounds with active agent forming fine dispersion throughout the film composition to be delivered to the desired area of skin (page 1, lines 78-88). The film forming water soluble compounds are selected from polyvinyl pyrrolidone, polyvinyl alcohol or water soluble cellulose ether page 2, lines 5-16). The reference teaches that films that include polyvinyl alcohol and water soluble cellulose ether are inherently adhesive and do not require addition of additional adhesive (page 3, lines 70-75). The film is transparent (page 5, examples 1

and 2). The film layer may be covered by protective layers that are removed before use (page 2, lines 124-130). The film is wetted or moistened before use, and when wetted it dissolves, i.e. removed from skin (page 4, lines 1-7). The film delivers the active agent for period of 21-25 minutes (page 8, lines 96-97). Wetting the patch or wetting the skin will achieve the same result.

Although GB '837 teaches soluble film that is expected to be capable to be removed by rinsing, and further teaches dissolution of the film when wetted, i.e. dissolves and disintegrates, however, the reference does not explicitly teach the step of removing the patch by rinsing.

US '047 teaches patch comprises water-soluble adhesive sheet that can be applied to the skin and have adhesiveness such that if falls off from the skin upon wetting (abstract; col.2, lines 62-64; col.11, lines 13-15). The water-soluble polymers included polyvinyl pyrrolidone (col.3, lines 5-8). The reference teaches the patch un-necessary to peel of the patch from the skin after using which brings good feel on use (col.11, lines 39-42). The patch of polymer sheet further comprises active agents including anti-inflammatory agent and sodium salicylate (col.6, lines 59-64; col.7, lines 61-63; col.8, lines 7-10, 22; col.10, line 25).

Although GB '837 teaches fine dispersion of the active agent throughout the water soluble film, however, the reference does not explicitly teach encapsulation of the active agent as instantly claimed by claims 30, 33, 35, 42, and 48.

US '798 teaches transdermal device comprises matrix comprising active agent dispersed in microencapsulated form to control the release of the active agents

(abstract; col.1, line 67-col.2, line 2). The drug release into the matrix is controlled by selecting the microcapsules as hydrophilic or hydrophobic (col.2, lines 9-15).

US '779 teaches a released control transdermal therapeutic system achieved by microencapsulating the active agent using spray drying technique (abstract; col.2, lines 29-32; col.7, lines 57-59; col.8, lines 20-25, 39-42)

Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)

Therefore, at the time of the invention it was known to deliver active agent to the skin from water soluble transparent film when the film is wetted and dissolved as disclosed by GB '837. At the time of the invention it was known to apply water soluble film to the skin to deliver active agent and remove it by rinsing in water without peeling from skin as disclosed by US '407. It was further known at the time of the invention to encapsulate the active agent in spray-dried microcapsules to control the release of the active agent as disclosed by US '798 and US '779.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver active agent to the skin using water soluble transparent film that is wetted before as disclosed by GB '837, and further remove the film with rinsing with water as disclosed by US '407. One would have been motivated to do so because US '407 remove the patch from skin without need to peel it off after use which brings good feel in use. One would reasonably expected delivery of active agent

to the skin from water soluble polymer transparent film that is wetted before use and removed by rinsing with water wherein the patch brings pleasant feel in use.

Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver active agent to the skin using water soluble transparent film that is wetted before use and removed after use by rinsing as disclosed by GB '837 combined with US '407, and further microencapsulate the active agent in hydrophobic material as disclosed by US '798 and select spray-dried microcapsules as disclosed by US '779. One would have been motivated to do so because US '798 teaches that microcapsules control the release of the active agent and because US '779 teaches that spay drying microencapsulation is preferred technique to provide controlled release of encapsulated drugs from the transdermal device. One would have been reasonably expected delivery of active agent to the skin from water soluble polymer transparent film comprising spray-dried microencapsulated active agents to be delivered to the skin in a controlled release manner.

Resolving the level of ordinary skill in the pertinent art (MPEP *§ 2141.012)*

One skilled in the art a the time of the invention would be motivated to deliver active agents to skin using water soluble polymer film that is wetted before use to dissolve and release the active agent and removed from skin by rinsing after use, and further encapsulate the active agent to provide control the release of the active agent. The invention as a whole is taught by the combined teaching of the prior art, and considered prima facie obvious in the meaning of 35 USC § 103 (a).

7. Claims 9 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '837 combined with US '047, US '798 and US '779 and further in view of US 6,497,887 ('887)

The combined teachings of GB '837, US '047, US '798 and US '779 are discussed as set forth in this office action.

However GB '837 does not explicitly teach the salicylic acid as claimed by claim 9, or an anti-acne agent as claimed by claim 24. Salicylic acid is an anti-acne agent.

US '887 teaches polymeric membrane in form of matrix dissolvable upon wetting and can be used to deliver biologically active agents to the skin (abstract; col.3, line 45). The membrane may be wetted before use or applied to wetted skin (col.4, lines 63-67). The membrane permits sustained delivery of active ingredients to the skin and does not have to be peeled or washed off the skin, but simply dissolve (col.6, lines 11-16). The membrane is made of water-soluble polymers such as starches (co1.1, lines 60-67;

col.2, lines 21-34). The membrane comprises film forming polymers such as hydroxypropyl cellulose and polyvinyl pyrrolidone and polyvinyl alcohols (col.3, lines 18-30). The active agents include salicylic acid and anesthetic (col.5, lines 10-20, 23-25, 33-40, 44, 59-67; col.7, claim 6).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver active agent to the skin using water soluble transparent film that is wetted before use and removed after use by rinsing wherein the film comprises microencapsulated active agent as disclosed by the combination of GB '837 with US '407, US '798 and US '779, and replace the active agent by salicylic acid as disclosed by US '887. One would have been motivated to do so because US '887 teaches that salicylic acid can be delivered by water soluble film that is applied to skin. One would have been reasonably expected delivery of salicylic acid to the skin from water soluble polymer transparent film comprising spray-dried microencapsulated salicylic acid to be delivered to the skin in a controlled release manner to the skin in need of such treatment.

Response to Arguments

8. Applicant's arguments with respect to claims 9, 24, 30, 31, 33, 35, 41, 42, 48 and 49 have been considered but are moot in view of the new ground(s) of rejection.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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